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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/644,937

08/23/2000

Anthony Nicholls

9476-003-999

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09/10/2002

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EXAMINER

MARSCHER, ARDIN H

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 09/10/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/644,937

Applicant(s)

Nicholls

Examiner
Ardin Marschel

Art Unit
1631



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jun 10, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-139 is/are pending in the application.
- 4a) Of the above, claim(s) 1-21, 23-26, and 30-139 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22 and 27-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-139 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on Aug 23, 2000 is/are a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All b) ☐ Some* c) ☐ None of:

- ☐ Certified copies of the priority documents have been received.
- ☐ Certified copies of the priority documents have been received in Application No. _____.
- ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449) 3 sheets
- ☐ Interview Summary (PTO-413) Paper No(s). _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other:

Applicant's election without traverse of Group II (Specie A), claims 22 and 27-29 Paper No. 8, filed 6/10/02, is acknowledged.

The Abstract of the Disclosure is objected to because it is too long. Applicant is required to submit a new abstract which is 150 words in length or less on its own separate sheet of paper. Correction is required. See M.P.E.P. § 608.01(b).

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The present title is directed to a method and apparatus for evaluating molecular similarity. This conflicts with the elected subject matter which is directed to only a method, but also is directed to a method of determining a shape space of a set of molecules.

If applicant desires priority based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph. The status of non-provisional application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. _____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow

the filing date of the parent application.

NEW MATTER:

Claims 22 and 27-29 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Comparison of instant claims 22 and 27-29 with the instant specification as filed revealed that the closest disclosure of a method for determining a shape space of a set of molecules, as in instant claim 22, is set forth on pages 38-39 as steps (a) - (f) wherein Figure 6 is also cited. These steps, however, are different from newly submitted claim 22 in that step (a) is missing from instant claim 22. Instead, the generic line 3 of claim 22 only requires the choosing of an initial set of N molecules without further limitation. In contrast, step (a) on page 38-39 discloses the calculation of maximal overlap of all pairs of N structures and noting that N will not be the total set of molecules at the end of said step (a). Thus, the end of step (a) would result in less than N molecules chosen for further analysis. Similarly, Figure 6 indicates choices at the first step in the method which are not present in claim 22.

Consideration of the remainder of the instant specification has

failed to reveal a shortened method as now set forth in claim 22. Thus, claim 22 lacks written description as filed and thus contained NEW MATTER as being directed to a method which has not been disclosed as filed. Claims 27-29 utilize and depend from claim 22 directly or indirectly and thus also contain the above described NEW MATTER.

SCOPE OF ENABLEMENT REJECTION:

Claims 22 and 27-29 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for the construction step (c) according to Blaney et al. and diagonalizing procedure (e) according to Blaney et al. in the specification on page 39 (subject, however, also to the below rejection based on improper incorporation by reference), does not reasonably provide enablement for any construction utilizing a generic distance geometry technique (claim 22, lines 7-8) or any generic diagonalizing of G to obtain a set of positions in N-1 dimensional space (claim 22, lines 9-12). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CAFC

1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

The above noted steps of construction and diagonalization are presumably described in Blaney et al. but not elsewhere in the instant specification. It is noted that both of these steps are distance matrix calculations in at least N-1 dimensional space which is clearly of significant complexity. It should be noted that this rejection, regarding the diagonalization of G step, is directed to the entirety of lines 9-12 and not simply to an issue of diagonalizing a matrix. This note is added to acknowledge that the diagonalization of a matrix is a well known mathematical technique. The issue regarding said step in said lines 9-12 is the diagonalizing to obtain a set of positions in N-1 dimensional space etc. in lines 9-12. Under 35 U.S.C. § 112,

first paragraph, the enablement of an invention requires applicant to set forth how to use the invention. In the constructing step of constructing G from D, one matrix G is being constructed from D. It is clear that converting one matrix to another is an undirected and random process if not defining by a conversion algorithm and thus unpredictable as to what is the result or use thereof. Apparently a distance geometry technique is utilized in claim 22 for said matrix conversion. Since the only matrix conversion seems to be set forth in Blaney et al., and any other undefined matrix conversion is thus unpredictable, then the only enabled conversion is that of the reference (subject to the improper incorporation by reference rejection below). Similarly, the diagonalizing step to obtain a set of position in N-1 dimensional space has only been described apparently in Blaney et al. (again subject to the improper incorporation by reference rejection below), any other undefined method is random and unpredictable and not enabled.

LACK OF ENABLEMENT:

Claims 22 and 27-29 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether a disclosure

would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

In claim 22, lines 7-8, a metric matrix G from D is constructed according to a distance geometry technique. In considering the instant specification, it is noted that this construction technique is described on page 39, lines 9-13, as being performed via a printed publication. This construction technique is clearly required in order to perform this step and therefore is essential subject matter for the performance of claim 22 and 27-29 due to depending directly or indirectly from claim 22 and utilizing the claim 22 method. The incorporation by

reference of essential subject matter lacks enablement as to this essential subject matter and is thus improper. See the following paragraph. It is noted that page 39, lines 16-20, also cite essential subject matter, directed to diagonalizing G to obtain a set of positions in N-1 dimensional space that reproduce the distances in the matrix D, via incorporation by reference to a printed publication which is also improper for the same reason as for the above noted incorporation by reference. Also, see the following paragraph.

The incorporation of essential material by reference to a foreign application or foreign patent or to a publication inserted in the specification is improper. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or applicant's attorney or agent, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. *In re Hawkins*, 486 F.2d 569, 179 USPQ 157; *In re Hawkins*, 486 F.2d 579, 179 USPQ 163; *In re Hawkins*, 486 F.2d 577, 179 USPQ 167.

LACK OF COMMENSURATE SCOPE:

Claims 22 and 27-29 are rejected, as discussed below, under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 22 and thus 27-29 via dependence is not commensurate in scope with the method set forth on pages 38-39 of the instant specification and thus is vague and indefinite due to this lack of commensurateness. Clarification via clearer claim wording is

requested.

NON-STATUTORY SUBJECT MATTER REJECTION:

35 U.S.C. § 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Claims 22 and 27-29 are rejected under 35 U.S.C. § 101 because the claims are directed to non-statutory subject matter.

As set forth in the MPEP § 2106: The claimed invention as a whole must produce a "useful, concrete and tangible" result to have a practical application. "A process that consists solely of the manipulation of an abstract idea is not concrete or tangible. See *In re Warmerdam*, 33 F.3d 1354, 1360, 31 USPQ2d 1754, 1759 (Fed. Cir. 1994). See also *Schrader*, 22 F.3d at 295, 30 USPQ2d at 1459" and "...a process consisting solely of mathematical operations, i.e., converting one set of numbers into another set of numbers, does not manipulate appropriate subject matter and thus cannot constitute a statutory process."

The computation and analysis steps of claims 22 and 27-29 are mathematical operations and do not recite concrete and tangible steps, and therefore the claims do not recite statutory subject matter. The invention per se is a mathematical process and simply utilizing a computer as in claims 28 and 29 still does not change the basic character of the invention. Thus, claims 28

and 29 are included in this rejection.

The disclosure is objected to because of the following informalities:

On page 12, lines 27 and 28, of the specification a Figure 7 is briefly described. This conflicts with the Figures because there are Figures 7A and 7B, but no Figure 7. Each separate Figure and subpart must be separately described in the section entitled "Brief Description of the Drawings".

Page 34 of the specification is objected to as it contains single spaced lines. The specification is required to be either 1 1/2 or double spaced.

Correction is required.

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703)308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

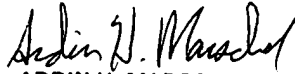
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Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

September 6, 2002


ARDIN H. MARSCHEL
PRIMARY EXAMINER